NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Neuromuscular Blocking Agents

Medicaid and Health Choice
Amended Date: August 15, 2014

Therapeutic Class Code: S7A
Therapeutic Class Description: Neuromuscular Blocking Agents

Medication	Generic Code Number(s)
Botox (onabotulinumtoxin A)	23360, 28011
Myobloc (rimabotulinumtoxin B)	12245, 12246, 12247
Dysport (abobotulinumtoxin A)	23361, 29243
Xeomin (incobotulinumtoxin A)	27767, 28953

Eligible Recipients
Medicaid recipients must be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NCHC recipients, ages 6 through 18 years of age, must be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure
a. that is unsafe, ineffective, or experimental/investigational.
b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to

correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements
a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

***Basic Medicaid and NC Health Choice Billing Guide*:**
http://www.ncdhhs.gov/dma/basicmed/

EPSDT provider page: http://www.ncdhhs.gov/dma/epsdt/

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Recipients ages 6 through 18 years of age

EPSDT does not apply to NCHC recipients. If a NCHC recipient does not meet the clinical coverage criteria within **the Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC recipient will be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes will be covered for NCHC recipients.

Criteria:

Onabotulinumtoxin A (Botox):

Onabotulinumtoxin A (Botox) shall be covered as follows:

FDA-Indications:

- Blepharospasm
- Disorders of eye movement (strabismus)
- Spasmodic Torticollis, secondary to cervical dystonia
- Upper limb spasticity in adults
- Chronic Migraine (Botox ONLY) age 18 and older:
    - 15 or more days each month with headache lasting 4 or more hours

      and

    - tried and failed prophylactic medications from at least 3 different drug classes (beta blockers, calcium channel blockers, tricyclic antidepressants and anticonvulsants) each for at least 3 months of therapy

or

- has a documented contraindication, intolerable side effects, or allergy to prophylactic medications (beta blockers, calcium channel blockers, tricyclic antidepressants and anticonvulsants)

  and

- Initial approval will be for 6 months
- <u>For continuation of therapy:</u>
  - assessment of response should be noted after the first 2 injections (6 months)
  - average number of headache days decreased by 6 or more days from the patient's baseline headache frequency

- Urinary Incontinence and Overactive Bladder (Botox ONLY):
  - due to detrusor overactivity (idiopathic or associated with neurologic conditions)

    and
  - tried and failed an anticholinergic medication

    or
  - has a documented contraindication, intolerable side effects, or allergy to anticholinergic medications

- Severe axillary hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met:
  - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
  - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant

<u>Off-Label Indications:</u>

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated

- Spasticity (e.g., from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia , hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, and stroke)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Achalasia and cardiospasm
- Secondary focal hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Abobotulinumtoxin A (Dysport):

Abobotulinumtoxin A (Dysport) shall be covered for the following conditions:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia

Off-label indications:

- Blepharospasm
- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated
- Spasticity (e.g., from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, stroke, and upper limb spasticity in adults)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Disorders of eye movement (strabismus)
- Achalasia and cardiospasm
- Secondary focal hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Severe axillary hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met:
    - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
    - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant

- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Incobotulinumtoxin A (Xeomin):

Incobotulinumtoxin A (Xeomin) shall be covered as follows:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia
- Blepharospasm

Off-label indications:

- Sialorrhea
- Chronic anal fissure refractory to conservative treatment
- Esophageal achalasia recipients in whom surgical treatment is not indicated
- Spasticity (e.g., from multiple sclerosis, neuromyelitis optica, other demyelinating diseases of the central nervous system, spastic hemiplegia, quadriplegia, hereditary spastic paraplegia, spinal cord injury, traumatic brain injury, stroke, and upper limb spasticity in adults)
- Schilder's disease
- Congenital Diplegia – Infantile hemiplegia
- Infantile cerebral palsy, specified or unspecified
- Disorders of eye movement (strabismus)
- Achalasia and cardiospasm
- Secondary focal hyperhydrosis (Frey's syndrome)
- Hemifacial spasms
- Severe axillary hyperhidrosis due to axillary hyperhidrosis. All of the following criteria must be met:
    - The recipient has documented medical complications due to hyperhidrosis, (i.e., skin maceration with secondary skin infections or significant constant disruption of professional life); and
    - Documentation that the recipient has failed a 6-month trial of conservative management including the use of topical aluminum chloride or extra strength antiperspirant
- Idiopathic (primary or genetic) torsion dystonia
- Symptomatic (acquired) torsion dystonia
- Laryngeal dystonia and adductor spasmodic dysphonia

Rimabotulinumtoxin B (Myobloc):

Rimabotulinumtoxin B (Myobloc) shall be covered for the following conditions:

FDA indications:

- Spasmodic Torticollis, secondary to cervical dystonia

Off-label indications:

- Sialorrhea

There are several botulinum toxins, currently A through G. Only A and B are now FDA-approved and commercially available. This policy deals *only* with onabotulinumtoxin A (Botox), abobotulinumtoxin A (Dysport), incobotulinumtoxin A (Xeomin) and rimabotulinumtoxin B (Myobloc). These share certain properties, and some FDA approvals, as well as certain off-label uses that are addressed in this policy. However, these agents are *not* identical, and have differing therapeutic and adverse event profiles. Furthermore, units and dosing are not equivalent, so they are not directly interchangeable with one another. It is expected that physicians familiar with and experienced in use of these agents will utilize evidence-based medicine to select the appropriate drug and dose regimen for each recipient, condition, and use.

Procedures:

1) Not approved for cosmetic purposes

2) Approval length up to 12 months

3) Dosage limitations for onabotulinumtoxin A (Botox): the cumulative dosage should not exceed 600 units per 90 days.

4) Dosage limitations for rimabotulinumtoxin B (Myobloc): 10,000 units per 12 weeks (84 days).

5) Dosage limitations for abobotulinumtoxin A (Dysport): 1000 units per 12 weeks (84 days)

6) Dosage limitations for incobotulinumtoxin A (Xeomin): 500 Units per 12 weeks (84 days)

References:

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3. Solstice Neurosciences, Inc. Myobloc package insert. South San Francisco (CA); Revised November 2004.

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